510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k060354

B. Purpose for Submission:

New device

C. Measurand:

Benzodiazepine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid Benzodiazepine Urine Test

G. Regulatory Information:

1. Regulation section:

   862.3170

2. Classification:

   Class II

3. Product code:

   JXM

4. Panel:

   91, Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Acro Rapid Benzodiazepine Urine test is a lateral flow, rapid immunoassay for the qualitative detection of Oxazepam in human urine at a cutoff of 300 ng/mL. The test is used to obtain a visual qualitative result and is intended for laboratory use only.

   The assay provides only preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more

specific alternate chemical method is needed. Gas Chromatography /Mass Spectroscopy (GC/MS) analysis is preferred.

3. Special conditions for use statement(s):

   This assay provides only preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography /Mass Spectroscopy (GC/MS) analysis is preferred.

   For laboratory use only.

4. Special instrument requirements:

   Not applicable, as the device is a visually-read single-use device

I. Device Description:

Acro Rapid Benzodiazepine Urine Test is a one-step immunoassay in which a chemically labeled drug (Oxazepam-BSA conjugate) competes with Benzodiazepine and its metabolites in urine for limited antibody binding sites. The test device contains a membrane strip, which is pre-coated with oxazepam-protein conjugate at the test band region of the membrane strip. A wicking pad containing anti-Benzodiazepine monoclonal antibody-colloidal gold conjugate is placed at one end of the membrane. The device contains a control region which has a different antigen/antibody from the test region. The device is for single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Ameditech ImmunTest Drug Screen Benzodiazepine

. 2. Predicate 510(k) number(s):

   k050186

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Principle	Immunochromatographic Assay	Immunochromatographic Assay
Tracer	Antibody-Colloidal Gold Conjugate	Antibody-Colloidal Gold Conjugate
Intended Use	To detect benzodiazepine in human urine	To detect benzodiazepine in human urine
Cutoff concentration	300 ng/mL	300 ng/mL

Differences	Differences	Differences
Item	Device	Predicate
Incubation Time	5-10 minutes @ Room Temperature	5 minutes @ Room Temperature
Separation System	BSA Conjugate	BTG Conjugate

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The Acro Rapid Benzodiazepine test is based on the principle of competitive immunochemical reaction between an immobilized drug-protein conjugate and the drug or drug metabolites, which may be present in the urine sample for limited binding sites for the drug/drug metabolites of a labeled drug antibody. When sample is applied to the test device, the sample migrates by capillary action through the device. Benzodiazepine, if present in concentration below the cutoff level, the anti-drug antibodies in colloidal gold conjugate will bind to the drug-protein conjugate coated in the test line (in the test region) to form a line, a negative result. No line will form if the sample contains drug at the cutoff level or higher, because it will compete with drug-protein conjugate with colloidal gold conjugate (a preliminary positive result). Each device contains a procedural control which indicated that the correct volume of sample was added. Formation of a line in the control region should always appear if the proper volume is added regardless of the presence or absence of drug or drug metabolite in the urine specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The reproducibility of the device was evaluated at four different sites. Each site tested the device against blind-labeled urine controls contain 0, 150, 225, 375, 450 and 600 ng/mL benzodiazepine. A total number of 60 determinations were made for each concentration spread over the four sites. Reproducibility study data is presented below:

Site	0 ng/mL		150 ng/mL		225 ng/mL		375 ng/mL		450 ng/mL		600 ng/mL	
	#	Result	#	Result	#	Result	#	Result	#	Result	#	Result
1	15	15-	15	15-	15	4+/11-	15	15+	15	15+	15	15+
2	15	15-	15	15-	15	1+/14-	15	14+/1-	15	15+	15	15+
3	15	15-	15	15-	15	1+/14-	15	12+/3-	15	15+	15	15+
4	15	15-	15	15-	15	1+/14-	15	14+/1-	15	15+	15	15+
Total	60	60-	60	60-	60	7+/53-	60	55+/5-	60	60+	60	60+

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Procedural controls are included in the test strip of the device. A line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume was added to the device.

External control materials are not supplied with this test; however the labeling includes a recommendation that external positive and negative controls be tested to ensure proper kit performance. User should follow local, state and federal guidelines for testing QC material.

Stability:

Accelerated studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 15 – 30 ºC product is good until expiration date which is 2 years.

Real time studies have been conducted and are on-going.

d. Detection limit:

300 ng/mL, see the Precision/Reproducibility section (1a) above.

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug into drug-free normal urine. The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below. Note: Drugs or drug metabolites not listed may interfere with benzodiazepine assays and cause false results.

Compound	Concentration	
	ng/ml	Relative to Cutoff
Oxazepam	300	1 x
Alprazolam	2,000	0.65x
ά-Hydroxyalprazolam	1262	4.2x
Bromazepam	1562	5.2x
Chlordiazepoxide	1562	5.2 x
Chlordiazepoxide HCL	781	2.6x
Clobazam	98	0.33x
Clonazepam	781	2.6x
Clorazepate dipotassium	195	0.65x
Delorazepam	1562	5.2x

Compound	Concentration	
	ng/ml	Relative to Cutoff
Desalkylflurazepam	390	1.3x
Diazepam	195	0.65x
Estazolam	2500	8.3x
Flunitrazepam	390	1.3x
(+/-) Lorazepam	1562	8.3x
RS-Lorazepam glucuronide	156	0.52x
Midazolam	12500	41.7x
Nitrazepam	98	0.33x
Norchlordiazepoxide	195	0.65x
Nordiazepam	390	1.3x
Oxazepam	300	1x
Temazepam	98	0.33x
Triazolam	2500	8.3x

Substances unrelated to Benzodiazepine were first added to a pool of drug free urine samples to concentrations levels that are not likely to be found in urine. Most substances were tested at 100 ug/mL except for ascorbic acid (500 ug/mL), glucose (500 ug/mL) , hemoglobin (500 ug/mL), and ibuprofen (200 ug/mL). Samples containing these substances were negative with the test device.

In addition, the same substances were added to two specimens of pooled drug free urine and with spiked oxazepam at 150 ng/ml and 600 ng/ml and tested with the rapid test device. Samples prepared in 150 ng/ml oxazepam tested negative and those prepared in 600 ng/ml oxazepam tested positive. The results show these substances do not interfere with the assay. Below is a partial list of the substances tested. The complete list is contained in the package insert.

Acetaminophen	*Estrone*	*Penicillin-G*
L-Ascorbic Acid	*Furosemide*	*Pentobarbital*
Aspartame	*Glucose*	*Perphenazine*
Atropine	*Hemoglobin*	*Phencyclidine*
Benzilic Acid	*Ibuprofen*	*β -Phenylethylamine*
Bilirubin	*(+/-)-Isoproterenol*	*Procaine*
Caffeine	*Ketamine*	*Quinidine*
Chlorquine	*Labetolal*	*Ranitidine*
Chloramphenical	*Loperamide*	
(+/-)Chlorpheniramine	*MDE*	

Drug sample solutions with 50% below and 50% above the cutoff concentration were adjusted to a range of 4 to 9 in 1 pH unit increments. Each sample was run ten times at each concentration with the Acro Rapid Benzodiazepine Urine Test. Altering the pH of the sample did not affect the expected results of the test.

Drug sample solutions with 50% below and 50% above the cutoff concentration were adjusted to a specific gravity ranging from 1.003-1.04. Each sample was run ten times at each concentration with the Acro Rapid Benzodiazepine Urine Test. Altering the specific gravity of the sample did not affect the expected results of the test.

f. Assay cut-off:

Analytical performance of the device around the cutoff is described in Section M.1., above.

2. Comparison studies:

a. Method comparison with predicate device:

The new device was compared to the reference method, Gas Chromatography/Mass Spectrometry (GC/MS) using one hundred thirty unaltered clinical urine samples (70 negative and 60 positive). The studies included an adequate number of samples that contained drugs near the cut-off concentration of the assay.

New Device Results	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	High Positive (> +50%)
Positive	0	6	13	25
Negative	70	10	6	0
% agreement	100%	63%	68%	100%

b. Matrix comparison:

Not applicable; this device is only for use with urine samples

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.